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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,705	06/25/2003	Kent Harrison	10527-454001	3440

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EXAMINER
JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SA

Office Action Summary	Application No.	Applicant(s)	
	10/603,705	HARRISON, KENT	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 35-43* is/are pending in the application.

4a) Of the above claim(s) *5,6,19-22,37 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-18,23,24,35,36,38-41 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *011405*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 7-18, 23, 24, 35 and 35 have been considered but are moot in view of the new ground(s) of rejection.

The indicated allowability of claims 38 and 39 is withdrawn in view of the newly discovered reference to Lane et al. Rejections based on the newly cited reference(s) follow.

Due to the new rejections, no generic claim is in condition for allowance so the restriction remains appropriate.

New claim 43 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 35, 38, 39, 40 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,575,966 to Lane et al. Lane et al. disclose an elongated catheter device for endovascular insertion with a balloon at the distal end for directly cooling tissue (abstract). The balloon is inflated (deployed) using cooling medium to contact the tissue to be treated. The catheter is disclosed as having a guidewire for navigation through blood vessels to the treatment site (Col. 1, lines 25-30) which may be within a cardiac chamber (Col. 7, line 47) or cooling the ostium (col. 7, line 61). Lane et al. further disclose the use of phase change or expansion in the balloon for cooling (Col. 1, line 55).

Regarding claims 35, 38, 39, 40 and 43, the method of use is clearly inherent in the device structure and disclosure. The catheter is navigated through a blood vessel and the balloon is inflated (deployed) to cool the target tissue. It must be positioned properly prior to deployment in order to cool the tissue as disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4, 10-18, 23, 36 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,575,966 to Lane et al. in view of U.S. Patent 5,799,661 to Boyd et al. Lane et al. are discussed above, but do not teach a deployable cooling structure with a pad like structure and a sheath longitudinally movable over the deployable structure. Boyd et al. teach a device for cooling tissue comprising an elongate shaft (Fig. 42, # 233) with a deployable cooling structure at its distal end (Fig. 42, # 231), delivered to the treatment site via a sheath (Fig. 42, # 239). The flexible heat exchanger (231) is collapsible to a pre-deployed position which can easily fit through an access port into the chest of the patient. The flexible heat exchanger is attached to the distal end of an elongated tubular shaft (233). An inflow lumen (234)extends through the tubular shaft and is fluidly connected to the flexible heat exchanger. A return lumen (235) extends through the tubular shaft parallel to the inflow lumen. The lumens may be formed integrally with the tubular shaft. The proximal ends of the inflow lumen and the return lumen are adapted for attachment to a circulating pump and a reservoir of cooling fluid (Col. 21, lines 5-25). The flexible heat exchanger is interpreted as a patch and the shaft is longitudinally movable with the sheath. The flexible heat exchanger is made from two sheets of

flexible plastic which are heat sealed or RF sealed together to form a serpentine cooling path (232) through the heat exchanger. Preferred materials for manufacturing the flexible heat exchanger 231 include polyurethane, vinyl, polypropylene, nylon, etc. The flexible heat exchanger may have a flexible backbone (frame) which extends from the distal end of the tubular shaft to the distal edge of the heat exchanger. The flexible backbone may be made from a flexible polymer, elastomer, or a resilient metal wire, such as spring temper stainless steel or a superelastic nickel/titanium alloy, or a composite of metal and plastic. The flexible heat exchanger is rolled, folded or twisted and placed in an introducer sheath 239 in the pre-deployed position (Col. 21, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the deployable cooling structure as taught by Boyd et al in place of the deployable balloon of Lane et al. as an alternative equivalent deployable cooling means. The cooling of body tissue not easily accessible is common to both inventions, making it obvious to look to other inventions that teach delivery of cooling means to such inaccessible areas.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,575,966 to Lane et al. in view of U.S. Patent 5,799,661 to Boyd et al. Both are discussed above, but do not disclose dual patches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an additional patch, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,575,966 to Lane et al. in view of U.S. Patent 5,799,661 to Boyd et al. and further in view of U.S. Patent Application Publication US 2004.0030259 to Dae et al. Lane et al. and Boyd et al.

are discussed above, but do not teach a temperature sensor near the heat exchange area. Temperature sensors are well known and pervasive in the art as evidenced by the sensor of Dae et al. (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a temperature sensor as taught by Dae et al. in the device of Lane et al. as modified by Boyd et al. to monitor the process of cooling.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Henry M. Johnson, III
Primary Examiner
Art Unit 3739